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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/054,660	04/03/98	EGGERS	P

QM12/0823

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EXAMINER	
PEFFLEY, M	
ART UNIT	PAPER NUMBER
3739	8

DATE MAILED: 08/23/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/054,660	Eggers et al
Examiner	**Group Art Unit**
Michael Peffley	3739

☒ Responsive to communication(s) filed on *Jul 9, 1999*.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *41-119* is/are pending in the application.

Of the above, claim(s) *88-119* is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *41-61 and 63-87* is/are rejected.

☒ Claim(s) *62* is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). *7*

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Election/Restriction

Applicant's election without traverse of the invention of Group I, claims 41-87 in Paper No. 6 is acknowledged. Claims 88-119 have been withdrawn from further consideration.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 51, 59, 60 and 76 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 51 and 76 fail to provide any particular method step. Rather, these claims merely recite an electrode array with no particular structural cooperation between the electrode array and the device, and with no particular relevance to the method steps.

Claims 59 and 60 lack clear antecedent basis for "said region of the myocardium". It is unclear which region of the myocardium is being referenced.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 41-46, 51-55, 59, 60, 66-72, 76-81 and 87 are rejected under 35 U.S.C. 102(b) as being anticipated by Bales et al ('596).

Bales et al disclose an RF catheter device whereby an electrode is used to revascularize and "core" heart tissue (see column 12, lines 29-32). The device includes a catheter with a single or plurality of electrodes thereon, and means to provide an irrigation solution and means to remove tissue and fluid (i.e. aspiration). The device may be used in a monopolar mode with a patient plate return electrode (column 4, line 67 through column 5, line 2), or may be used in a bipolar mode with a return electrode located on the catheter proximal to the active electrode (see column 7). The method of using the device to revascularize or otherwise "core" tissue by providing high frequency current between the active and return electrodes is inherent to the structure and disclosure of Bales et al.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 47-50 and 73-75 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bales et al ('596) in view of the teachings of Aita et al ('096) and Aita et al ('152).

The Bales et al has been addressed previously. While Bales et al disclose that the catheter device may be used for revascularizing and coring cardiac tissue, there is no specific disclosure as to where the procedure is initiated (i.e. from within the heart or from the external surface of the art).

Aita et al disclose a catheter device for performing TMR procedures. The Aita et al devices utilize an alternative energy source (i.e. laser energy), but otherwise teach that it is generally known to perform revascularization procedure which are initiated either from within the heart (Aita et al '096) or on the external surface of the heart (Aita et al '152).

To have provided the Bales et al catheter device either within the heart or on the surface of the heart to perform the revascularization procedure would have been an obvious consideration for one of ordinary skill in the art, particularly since Aita et al teaches that such procedures may be performed from either location.

Claims 56-58, 61, 65 and 82-86 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bales et al ('596).

While Bales et al disclose the use of the catheter device for performing revascularization procedures and the provision of an irrigant to tissue, Bales et al fail to teach the specific size of the channels or the specific fluid used for irrigation.

The examiner maintains that the size of the channels is based on the size of the catheter device, and that the selected size of the catheter device would be an obvious selection for one of ordinary skill in the art. Further, the examiner takes official notice that catheter devices which employ a source of irrigation generally, or very often, use saline as the irrigant.

To have provided the Bales et al device in any reasonable size would have been an obvious design consideration for one of ordinary skill in the art. Further, to have used saline as the irrigation fluid in the Bales et al device would have been an obvious selection for one of ordinary skill in the art since saline is a very commonly used irrigant in such catheters.

Claims 63 and 64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bales et al ('596) in view of the teaching of Mueller et al ('164).

Again, Bales et al teaches of the use of the RF electrode catheter for performing revascularization procedures. However, Bales et al do not specifically teach of providing curved or substantially "U-shaped" channels in heart tissue.

Mueller et al disclose a similar catheter device which uses an alternative energy source (i.e. laser) to revascularize heart tissue. More specifically, Mueller et al teach of using the device to create non-linear and substantially U-shaped channels in heart tissue (see figures).

To have modified the Bales et al catheter to create curved channels in heart tissue would have been an obvious modification for one of ordinary skill in the art in view of the teaching of Mueller et al.

Allowable Subject Matter

Claim 62 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 41-87 are rejected under the judicially created doctrine of double patenting over claims 1-57 of U. S. Patent No. 5,873,855 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows: a method for performing TMR procedures using an RF electrode catheter.

Furthermore, there is no apparent reason why applicant was prevented from presenting claims corresponding to those of the instant application during prosecution of the application which matured into a patent. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Roth et al ('956), Negus et al (848) and Murphy-Chutorian ('714) all disclose various devices and methods for performing TMR procedures.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mike Peffley whose telephone number is (703) 308-4305. The examiner can normally be reached on Monday through Friday from 7:00 am to 4:30 pm.

In the event the examiner can not be reached or is absent from the Office, the examiner's supervisor, Linda Dvorak, can be reached at (703) 308-0994.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0858. The formal fax number for the Group is (703) 305-3590.

Michael Peffley/mp
Primary Examiner
Art Unit 3739
August 18, 1999

MICHAEL PEFFLEY
PRIMARY EXAMINER
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